DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Alan Morris
Manager, Product Development
Medtox Diagnostics, Inc.
1238 Anthony Rd.
Burlington, NC 27215

OCT 25 2005

Re: k050394
Trade/Device Name: Sure-Screen® Amphetamine, Sure-Screen® Benzodiazepine, Sure-Screen® Methamphetamine, Sure-Screen® Methadone, Sure-Screen® Opiate, Sure-Screen® Phencyclidine and Sure-Screen® Cannabinoids
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, JXM, LDJ, DIO, DJR, DJC, DJG, LCM
Dated: August 31, 2005
Received: September 1, 2005

Dear Mr. Morris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050394

Device Name: Sure-Screen® Amphetamine, Sure-Screen ® Benzodiazepine, Sure-Screen® Cocaine, Sure-Screen® Methamphetamine, Sure-Screen® Methadone, Sure-Screen® Opiate, Sure-Screen® Phencyclidine and Sure-Screen® Cannabinoids

Indications For Use:

The SURE-SCREEN Drugs of Abuse Test System uses immunochromatographic test strips for the rapid, qualitative detection of one or more of the following: Amphetamines, Benzodiazepines, Cocaine, Methamphetamine, Methadone, Opiates, Phencyclidine and THC (Cannabinoids) in human urine. It is intended for prescription point-of-care use including workplace settings, criminal justice or forensic settings, drug rehabilitation clinics, physician offices and laboratory settings. SURE-SCREEN is not for over-the-counter sale.

Operators that may use this device are defined as individuals with a minimum of a high school education with no formal laboratory training or experience. Individuals should also satisfy the following training and certification guidelines: (1)Training should be conducted by a qualified professional and include a demonstration of the SURE-SCREEN test system and (2) the use of quality assurance samples for monitoring and confirming the performance of the test system. Trainers should observe and confirm that the operator (3) uses proper technique when running a test sample and quality assurance samples, (4) has a basic understanding of test results, including a the potential for false positive and false negative results, (5) knows how to prepare a sample for shipment to the laboratory for confirmation testing, (6) has reviewed the information contained in the MEDTOX SURE-SCREEN Training and Certification Program (available at www.medtox.com and that the operator (7) minimally achieves a score of 80% on the written exam provided by MEDTOX .

Operators achieving a score of 80% will be provided with a certificate of training participation. Quality assurance samples appropriate for training are available from MEDTOX Laboratories Inc. Additionally, MEDTOX Technical Support will provide access to assistance from individuals who are experienced in the interpretation of drug testing results.

Sure-Screen detects drug classes at the following cutoff concentrations:

(AMP) Amphetamines (d-Amphetamine)	300 ng/mL

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(BZO) Benzodiazepines (Nordiazepam)	200 ng/mL
(COC) Cocaine (Benzoylecgonine)	100 ng/mL
(MAMP) Methamphetamine (d-Methamphetamine)	300 ng/mL
(MTD) Methadone (Methadone)	200 ng/mL
(OPI) Opiates (Morphine)	100 ng/mL
(PCP) Phencyclidine (Phencyclidine)	25 ng/mL
(THC) Cannabinoids (11-nor-9-carboxy-Δ^9-THC)	40 ng/mL

Many of the cutoff concentrations for these tests are below those recommended by SAMHSA. Additionally, many of these tests are positive at levels significantly below the claimed cutoff concentration. The rate of false positive results with tests having sensitivities this low has not been studied. However, the rate of false positives generally increases as the cutoff concentration of the test is lowered. See the Precision/Sensitivity section for more information.

The SURE-SCREEN drugs of abuse test system provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result.

It is the responsibility of those organizations required to follow Department of Transportation (DOT) or Substance Abuse Mental Health Services Administration (SAMHSA) Workplace Drug Testing Guidelines to determine that use of this product satisfies the criteria for workplace testing established under DOT and SAMHSA authority.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Evaluation and Safety

510(k) K050324